K021108
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## 510(k) SUMMARY – ESOP® HA Femoral Stem

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|---|---|
| **Submitter Name:** | Fournitures Hospitalieres Industrie |
| **Submitter Address:** | 6 rue Nobel, Z.I. de Kernevez<br>Quimper, France 29000 |
| **Contact Person:** | Christine Quendez |
| **Phone Number:** | + 33 2 98 55 68 95 |
| **Fax Number:** | +33 2 98 53 42 13 |
| **Date Prepared:** | 22 March 2002 |
| **Device Trade Name:** | ESOP® HA Femoral Stem |
| **Device Common Name:** | Femoral Stem |
| **Classification Name:** | Prosthesis, Hip, Femoral Component |
| **Predicate Devices:** | • FHI ESOP® S/C Femoral Stem, K964878<br>• Landos CORAIL Femoral Stem, K953111 |
| **Device Description:** | The ESOP® HA Femoral Stem consists of left and right configuration metaphysis parts in various size diameters, and diaphysis parts in various sizes. The ESOP® HA Femoral Stem instrument system is used for proper implantation of the device. The ESOP® HA Femoral Stem design includes: 10 left and right configuration metaphysis parts in various sizes diameters and cone angles, and 7 diaphysis parts of various sizes which are to be screwed into the extremity of the metaphysis part. |
| **Device Technological Characteristics and Comparison to Predicate Device(s):** | The ESOP® HA Femoral Stem is made of similar materials, is available in similar diameters and lengths, has a similar design, and the same indications for use as the predicate devices and other currently marketed femoral stems. |

**Performance Data:** Verification/validation and design control activities demonstrate the safety and effectiveness of the ESOP® HA Femoral Stem.

**Conclusion:** The ESOP® HA Femoral Stem is substantially equivalent to the claimed predicate devices and other currently marketed femoral stems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 3 2002

Fournitures Hospitalieres Industrie
c/o Dr. Andre Weith
Director, Pro-Active Healthcare
c/o PharmaNet, Inc.
815 Connecticut Avenue NW, Suite 800
Washington, D.C. 20006

Re: K021108
Trade/Device Name: ESOP® HA Femoral Stem
Regulation Number: 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: MEH
Dated: April 5, 2002
Received: April 5, 2002

Dear Dr. Weith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and

listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number (if known):** K021108 page 1 of 1

**Device Name:** ESOP® HA Femoral Stem

**Indications for Use:**

The ESOP® HA Femoral Stem is intended for use in degenerative and inflammatory arthritis of the hip joint, trauma, non-acute femoral neck fracture, revision of previously failed hip arthroplasties, and idiopathic avascular (osteo) necrosis where radiographic evidence shows there is sufficient sound bone to seat the prosthesis. This device is intended for cementless application.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021108

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)